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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,487	03/14/2007	Koichi Shudo	P29865	5124

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
08/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
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Office Action Summary	Application No.	Applicant(s)	
	10/577,487	SHUDO ET AL.	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/09/06, 2/10/09. 5/12/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 18 of copending Application No. 11/765,011. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claim 1 and claims 1 and 18 of application 11/765,011 claim the same compound, which is specifically claimed in the instant claim 1 and encompassed by the general formulas of claims 1 and 18.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 2 applicant claims that the compound of claim 1 is in “a releasable form”. This is unclear because any compound is in a releasable form as the compound will enter the patients system upon administration. Applicant has not defined a releasable form or otherwise indicated what this limitation is intended to mean. For example, does

applicant mean to claim a sustained release form or that the compound within a device such as a stent is in a releasable form or the compound is releasable from the vehicle in which the compound is administered? One of skill in the art would not be able to determine what applicant means by "releasable form" and thus claim 2 is rejected for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Muto et al. (EP 1352650 A1, cited on applicant's IDS).

In claim 1 applicant claims a medicament for treatment of restenosis comprising as an active ingredient a compound of formula I. It is noted that this is a composition claim and thus the intended use carries no patentable weight. The claims are a composition comprising the compound of formula I. Muto et al. teaches medicaments comprising a compounds of Formula (I) (Abstract), including the claimed as compound 50 (page 59). Thus Muto et al. anticipates claim 1.

In claim 2 applicant claims that the compound of claim 1 is in a "releasable form". As discussed above, any compound is in a releasable form as it compound will be

released into the patient upon administration. Furthermore Muto et al. teaches that compound 50 inhibited NF-kB activation (page 136) and thus was released into the subject's bloodstream. Thus claim 2 is also anticipated by Muto et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muto et al. (EP 1352650 A1, cited on applicant's IDS) in view of Callahan et al. (WO 99/65449, cited on applicant's IDS).

In claim 1 applicant claims a medicament for treatment of restenosis comprising the compound of formula I. As discussed above the intended use does not carry

patentable weight. However, even if it were to be given patentable weight, Muto et al. teaches the compound as compound 50 (page 59) and teaches it has activity inhibiting NF-kB activation (page 136). Callahan et al. teach that compounds which inhibit NF-kB activation can be used to treat restenosis (abstract) and thus claim 1 is unpatentable over Muto et al. in view of Callahan et al.

In claim 2, applicant claims the compound of claim 1, in a "releasable form". As discussed above, any compound can reasonably be interpreted as being in a releasable form. Furthermore, there is an obvious motivation for the compound to be formulated in a releasable form as the intended target is treatment of humans and the drug needs to release from whatever vehicle it is administered via into the body. Thus claim 2 is also unpatentable over Muto et al. in view of Callahan et al.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muto et al. (EP 1352650 A1, cited on applicant's IDS) in view of Callahan et al. (WO 99/65449, cited on applicant's IDS) in further view of Tang et al. (US 2003/0219877 A1).

In claim 3, applicant claims that the composition of claim 2 is an intravascular indwelling stent. Muto et al. does not teach stents, however such a stent is well known for treatment of diseases such as restenosis and atherosclerosis. Tang et al. teaches that compounds can be administered via stents to treat atherosclerosis (page 11, [0083]). Callahan teaches that both can be treated by NF-kB inhibitors (abstract) and thus it would be obvious to one of ordinary skill in the art at the time of the invention to formulate the compound of claims 1 and 2 in an intravascular indwelling stent for

treatment of restenosis or atherosclerosis. It is noted that this claim is also drawn to a composition and not a method of treatment. Thus any motivation to put the Compound of claim 1 in an intravascular indwelling stent is sufficient. Thus claim 3 is unpatentable over Muto et al. in view of Callahan et al. in further view of Tang et al.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/James D Anderson/

Examiner, Art Unit 1614